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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,315	03/08/2001	Archie Woodworth	1417 Y P 516	5264

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EXAMINER
MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,315	WOODWORTH ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *073001, 032102,061101, 092302*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

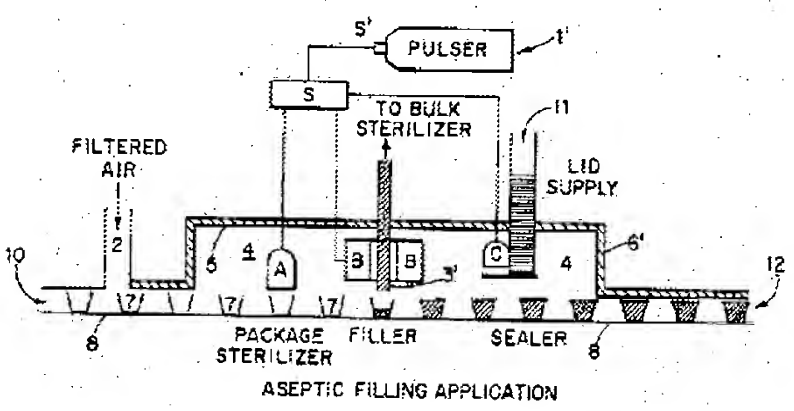
Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6, 8, 9, 39-42, 44-50, 52-58, 60, 64, 65, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Nablo (U.S. Patent No. 3,780,308).

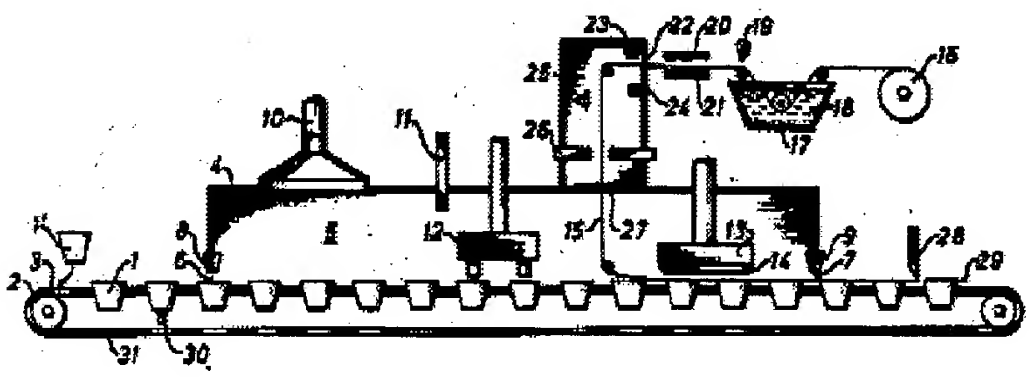
Nablo teaches an apparatus for producing a sterilized, prefilled plastic container wherein the apparatus includes an e-beam sterilizing station **4**, a sterile environment with a sterile ambient atmosphere comprising an opening at **B** for receiving a sterilized container, a transport mechanism **8**, a source of a sterile fluid substance and a filler at **3'**. The electron beam radiation generates ozone, which creates a sterile ambient atmosphere. See col.2, lines 60-61; col.5, lines 60-68. Dose levels of 1.5 Mrads (15 kGy) at current densities of 100 keV are employed by the sterilizer. See col.5, lines 7-8 and 45-46. In use, a container 7 is sterilized and immediately transferred through the sterile environment to filling station where the container is filled with a "medical solution"



and then sealed at **11**. For purposes of this rejection, a "medical solution" is considered to be any material having a medicinal purpose, such as food or water.

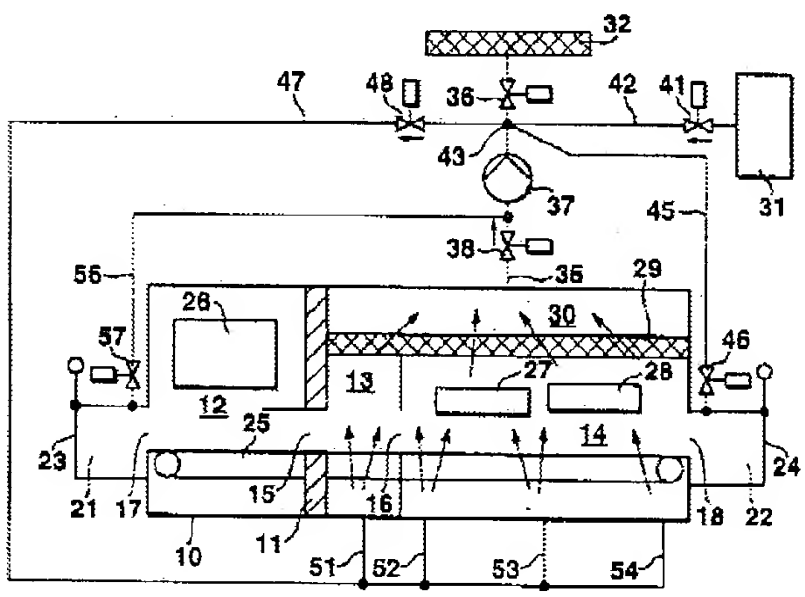
3. Claims 1-3, 39-41, 44-49, 52, 54-57, 60, 64, 65, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Rausing (U.S. Patent No. 4,014,158).

Rausing teaches an apparatus for filling and sealing plastic containers under aseptic conditions wherein the apparatus includes a sterilizing station **5**, a sterile environment with a sterile ambient atmosphere comprising an opening at **11** for receiving a sterilized container, a transport mechanism **2**, a source of a sterile fluid substance and a filler at **12**. The interior of the chamber is maintained in a sterile condition. See col.2, lines 57-65; col.3, line 68 to col.4, line 11. The sterilizer may be an electron beam radiation device, operating between 1 and 10 million eV (col.4, lines 12-16). In use, a container **1** is sterilized and immediately transferred through the sterile environment to filling station where the container is filled with a "medical solution" and then sealed at **13**. For purposes of this rejection, a "medical solution" is considered to be any material having a medicinal purpose, such as food or water.



4. Claims 10, 19, 20, 39, 44-47, 52, 54-56, 60, 64, and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Lemke et al (U.S. Patent No. 6,334,472).

Lemke et al teaches an apparatus for continuous in-line production of sterilized, prefilled containers wherein the apparatus includes a sterilizing station **26**, a sterile isolator comprising an opening **15** for continuously receiving a plurality of containers, a sterile ambient atmosphere adjacent the opening **15** (col.2, lines 3-9), a transport mechanism **25**, a source of sterile substance (vaccines, medicines, foods) and a filler **27**. As to the intended use of the device (e.g. "for sterilizing a syringe body", "for receiving a sterilized syringe body", etc.), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). In use, a container is provided to the apparatus where it is sterilized and immediately transferred through a sterile atmosphere to the filling station where it is filled with a vaccine, medicine, food, etc., and then sealed.



5. Claim 95 is rejected under 35 U.S.C. 102(b) as being anticipated by Heffernan et al (U.S. Patent No. 5,620,425).

Heffernan et al teaches a method of providing a plurality of syringe bodies, arranging the

bodies within a transfer tray (polypropylene carrier holder), sterilizing the syringe bodies and tray under Class 100 conditions, and filling the bodies while under Class 100 conditions. See Example 1: col.5, line 52 to col.7, line 14.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Nablo or Rausing as applied to claim 55 above, and further in view of Heffernan et al.

Both Nablo and Rausing teach the sterilizing of plastic containers (see Nablo, col.1, line 10; see Rausing, col.1, lines 52-57). However, neither disclose a step of weighing and inspecting the plastic container or forming the container by injection molding. Heffernan et al teaches a method of making prefilled containers wherein it is disclosed to injection mold the containers from polymeric materials (col.4, lines 41-53), followed by inspection (col.6, lines 3-11) and

sterilization. As it is known in the art of container molding and sterilization to using injection molding when forming polymeric containers and to inspect formed articles for size/shape conformity and cleanliness, it would have been obvious in the methods of either Nablo or Rausing.

9. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nablo or Rausing, as applied to claim 65 above, and further in view of Porfano et al (U.S. Patent No. 6,164,044).

Both Nablo and Rausing, while teaching forming a container from a polymeric material, fail to teach or suggest forming the container from a cyclic olefin copolymer. Porfano et al discloses that it was known in the art at the time of the invention to form containers intended for sterilizing and filling, of a cyclic olefin copolymer. See col.6, lines 44-47. As Porfano et al teaches that cyclic olefin copolymers do not require a clarifying agent, they would have been an economical choice for the containers of Nablo or Rausing.

10. Claims 5, 7, 43, 51, 59, and 97-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nablo.

With respect to claims 5, 7, 43, 51, 59, and 100, Nablo teaches employing a radiation dose of 15 kGy. However, Nablo also employs high dose rates, such as 10^{14} rad/sec (10^{9} kGy/sec). See col.5, lines 16-19. It is deemed obvious to optimize and even increase the radiation dose based upon the expected level of contamination, as such is easily obtained by routine experimentation.

As to claims 97-104, Nablo teaches a method wherein a plastic container 7 is sterilized with 15 kGy of e-beam radiation and immediately transferred through a sterile environment to a

filling station where the container is filled and then sealed at **11**. Although Nablo does not disclose providing a source of parenteral solution, it is deemed obvious to employ the method of Nablo to sterilize any liquid required to be aseptically packaged, as Nablo maintains a sterile environment. As to the pH of the solution, the method of Nablo would intrinsically produce the recited pH when sterilizing a parenteral solution.

11. Claims 4-7, 42, 50, 58, 59, 99, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rausing in view of Nablo.

While Rausing teaches the use of electron beam radiation to sterilize the containers **1**, a suitable dose is not disclosed. Nablo, however, discloses a similar method and apparatus wherein an e-beam dose of 15 kGy is delivered (col.5, line 45) for container sterilization but even higher dose rates are envisioned as well. As Nablo evidences that the claimed doses are effective in plastic container sterilization, it would have been obvious to use the doses of Nablo in the method and apparatus of Rausing.

12. Claims 10-20 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nablo in view of Lemke et al.

Nablo teaches an apparatus for continuously producing a sterilized, prefilled plastic container wherein the apparatus includes an e-beam sterilizing station **4**, a transport mechanism **8**, a source of a sterile fluid substance and a filler at **3'**. The electron beam radiation generates ozone, which creates a sterile ambient atmosphere. See col.2, lines 60-61; col.5, lines 60-68. Dose levels of 1.5 Mrads (15 kGy) at current densities of 100 keV are employed by the sterilizer. See col.5, lines 7-8 and 45-46. In use, a container 7 is sterilized and immediately transferred

through the sterile environment to filling station where the container is filled with a "medical solution" and then sealed at **11**. The apparatus lacks a sterile isolator.

Lemke et al discloses a similar apparatus wherein a sterile isolator receives containers through opening **15**. It would have been obvious to provide a sterile isolator in the apparatus of Nablo, as Lemke teaches that the incoming air for the isolator enclosure can be separately controlled and filtered.

Nablo teaches employing a radiation dose of 15 kGy. However, Nablo also employs high dose rates, such as 10^{14} rad/sec (10^{9} kGy/sec). See col.5, lines 16-19. It is deemed obvious to optimize and even increase the radiation dose based upon the expected level of contamination, as such is easily obtained by routine experimentation.

As to the intended use of the device (e.g. "for sterilizing a syringe body", "for receiving a sterilized syringe body", etc.), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nablo and Lemke et al as applied to claim 20 above, and further in view of Porfano et al.

The combination of Nablo with Lemke et al is silent with respect to a transfer holder for the containers. Porfano et al, however, teaches that it was known in the art to employ a transfer holder **94** that is sterilized with the containers. As such would have been an obvious means of protecting and enclosing for transport the sterile, filled containers, it would have been obvious to modify the apparatus of Nablo to include a transfer holder.

14. Claims 10, 11, 12, 19, 20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rausing in view of Lemke.

Rausing teaches an apparatus for filling and sealing plastic containers under aseptic conditions wherein the apparatus includes a sterilizing station **5**, a transport mechanism **2**, a source of a sterile fluid substance and a filler at **12**. The interior of the chamber is maintained in a sterile condition. See col.2, lines 57-65; col.3, line 68 to col.4, line 11. The sterilizer may be an electron beam radiation device, operating between 1 and 10 million eV (col.4, lines 12-16). In use, a container **1** is sterilized and immediately transferred through the sterile environment to filling station where the container is filled with a "medical solution" and then sealed at **13**. The apparatus lacks a sterile isolator.

Lemke et al discloses a similar apparatus wherein a sterile isolator receives containers through opening **15**. It would have been obvious to provide a sterile isolator in the apparatus of Rausing, as Lemke teaches that the incoming air for the isolator enclosure can be separately controlled and filtered.

As to the intended use of the device (e.g. "for sterilizing a syringe body", "for receiving a sterilized syringe body", etc.), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

15. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rausing and Lemke et al as applied to claim 20 above, and further in view of Porfano et al.

The combination of Rausing with Lemke et al is silent with respect to a transfer holder for the containers. Porfano et al, however, teaches that it was known in the art to employ a transfer holder **94** that is sterilized with the containers. As such would have been an obvious means of protecting and enclosing for transport the sterile, filled containers, it would have been obvious to modify the apparatus of Nablo to include a transfer holder.

16. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rausing and Lemke et al as applied to claim 20 above, and further in view of Nablo.

While Rausing teaches the use of electron beam radiation to sterilize the containers **1**, a suitable dose is not disclosed. Nablo, however, discloses a similar method and apparatus wherein an e-beam dose of 15 kGy is delivered (col.5, line 45) for container sterilization but even higher dose rates are envisioned as well. As Nablo evidences that the claimed doses are effective in plastic container sterilization, it would have been obvious to use the doses of Nablo in the method and apparatus of Rausing with Lemke et al.

17. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemke et al in view of Porfano et al.

Lemke et al teaches an apparatus for continuous in-line production of sterilized, prefilled containers wherein the apparatus includes a sterilizing station **26**, a sterile isolator comprising an opening **15** for continuously receiving a plurality of containers, a sterile ambient atmosphere adjacent the opening **15** (col.2, lines 3-9), a transport mechanism **25**, a source of sterile substance

(vaccines, medicines, foods) and a filler **27**. Lemke et al fails to disclose a means for transporting a container from a container forming process to the sterilizing station.

Porfano et al discloses that it was known in the art to combine a container forming process with a sterilization process. See Figure 11. As combining the two processes in a single system is more economical, it would have been obvious to connect the sterilization apparatus of Lemke et al with a container forming apparatus.

18. Claims 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemke et al and Porfano et al as applied to claim 30 above, and further in view of Nablo.

The combination of Lemke et al with Porfano et al fails to teach or suggest using electron beam irradiation for sterilization of the containers. Nablo discloses a similar apparatus for container sterilization wherein the containers are sterilized with e-beam radiation at dose levels of 1.5 Mrads (15 kGy) and current densities of 100 keV. See col.5, lines 7-8 and 45-46. As Nablo teaches that e-beam radiation achieves excellent sterilization results of the container while producing a sterile atmosphere for the entire apparatus, it would have been an obvious choice for the sterilization station of Lemke et al.

As set forth above, Nablo teaches employing a radiation dose of 15 kGy. However, Nablo also employs high dose rates, such as 10^{14} rad/sec (10^{9} kGy/sec). See col.5, lines 16-19. It is deemed obvious to optimize and even increase the radiation dose based upon the expected level of contamination, as such is easily obtained by routine experimentation.

19. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemke et al and Porfano et al as applied to claim 30 above, and further in view of Rausing.

The combination of Lemke et al with Porfano et al fails to teach or suggest using electron beam irradiation for sterilization of the containers. Rausing discloses a similar apparatus wherein containers are sterilized by an electron beam radiation device, operating between 1 and 10 million eV (col.4, lines 12-16). As Rausing teaches that the electron beam radiation maintains a sterile atmosphere within the enclosure, it would have been an obvious choice for the sterilization station of Lemke et al.

20. Claims 76-87, 90, 91, 93, 94, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Nablo or Rausing, both in view of Heffernan et al.

As set forth in paragraphs above, Nablo and Rausing both teach a method of sterilizing a polymeric (plastic) container, transferring the container through a sterile environment to a filler wherein the sterilized container is filled with a sterile fluid within an aseptic environment, and sealing the filled container within an aseptic environment. Neither of Nablo, or Rausing disclose forming and transferring formed containers to the sterilizing station.

Heffernan et al teaches that it was known in the art to form syringes using injection molding, to arrange them within a carrier holder, and to transfer them to a sterilizing station, all while maintaining the syringes under Class 100 (aseptic) conditions. See Example 1.

It would have been obvious to one of ordinary skill in the art to use the methods and apparatus of Nablo or Rausing, to sterilizing preformed syringes, as all operate under aseptic conditions, as required by Heffernan et al. Moreover, all would be capable of sterilizing syringes with only minor modifications to the apparatus.

21. Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nablo, Rausing, and Heffernan et al as applied to claim 87 above, and further in view of Porfano et al (U.S. Patent No. 6,164,044).

As to claim 88, both Nablo and Rausing, while teaching forming a container from a polymeric material, fail to teach or suggest forming the container from a cyclic olefin copolymer. Porfano et al discloses that it was known in the art at the time of the invention to form containers intended for sterilizing and filling, of a cyclic olefin copolymer. See col.6, lines 44-47. As Porfano et al teaches that cyclic olefin copolymers do not require a clarifying agent, they would have been an economical choice for the containers of Nablo or Rausing.

With respect to claim 89, both Nablo and Rausing teach the sterilizing of plastic containers (see Nablo, col.1, line 10; see Rausing, col.1, lines 52-57). However, neither disclose a step of weighing and inspecting the plastic container or forming the container by injection molding. Heffernan et al teaches a method of making prefilled containers wherein it is disclosed to injection mold the containers from polymeric materials (col.4, lines 41-53), followed by inspection (col.6, lines 3-11) and sterilization. As it is known in the art of container molding and sterilization to using injection molding when forming polymeric containers and to inspect formed articles for size/shape conformity and cleanliness, it would have been obvious in the methods of either Nablo or Rausing.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1275. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
28 June 2004